

Curriculum Vitae**Ranieri Nicola****Work Address:** Food and Drug Administration

Forensic Chemistry Center

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Cincinnati, OH 45237

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United States Citizen

Work Experience:

November 2014 - Present Biologist – GS-14 (Biologist)

January 2002 - GS-13-08 (Biologist)

January 1997 - GS-12-01 (Biologist)

December 1995 - GS-11-01 (Biologist)

December 1992 - GS-9-01 (Research Biologist)

December 1991 - GS-7-01 (Research Biologist)

August 1989 - GS-4-01 (Technician)

EDUCATIONAL BACKGROUND

1986-1990 University of Cincinnati; major: Biology; B.S. 1990 Cincinnati, OH.

PROFESSIONAL EXPERIENCE**August 1989 to present:****Forensic Chemistry Center / Food and Drug Administration**

- Perform 3D Image Analysis for an array of disciplines; Profilometry, Difference Measurements, Volumetric Measurements, Form Geometry of basic shapes, Roughness with high frequency wavelength, Waviness of low frequency wavelength, and Filtering a process of separating roughness and waviness.
- Lead inventor of the counterfeit detector hand-held device technology, versions CD1, CD2, CD3, CD3+, and CD4
- Lead trainer and responsible for mentoring, guiding, and the system troubleshooting responder for the Photo Documentation System for the FCC and FDA IMFs.
- Lead trainer and first responder, responsible for mentoring, directing, and the troubleshooting responder for the hand-held portable CDx for the Trace Examination Section, FDA CSOs and investigators, international scientist / other governmental agencies, academia, and ORA FCC CD3 Review Group.
- Responsible for mentoring and guiding the Print Process Identification, training leader for the Trace Examination Section, FDA CSOs and investigators, and international scientist / other governmental agencies.
- Perform Image Analysis, Print Identification, Alternate Light Source, SEM-EDX, microscopic and other physical analysis on samples submitted as part of OCI case work, ORA investigators and compliance officers, CDER, CFSAN, CDRH, and CBER and from other domestic agencies including DEA, Customs and Border Protection, state and local health and law enforcement and international agencies including CDC, MHRA, WWARN, LOMWRU, SEA Laos BFDI, WHO, USP CePAT, Health, and RIVM.
- Testified to the results of Image Analysis, Print Identification, Alternate Light Source, SEM-EDX, microscopic and other physical analysis on samples submitted in federal, state and local courts

- Performs applied research in the area of forensic science as it relates to foods, pharmaceuticals, cosmetics and medical devices.
- Presents analytical results at national conferences and to senior management
- Anti-Counterfeiting Lead analyst for the FCC's Trace Examination Section.

SUPERVISORY EXPERIENCE:

- Detail-Supervisor of Trace Examination Section (Nov. 2 to Dec. 31 2013) Plan, direct, and coordinate the work of scientists engaged in carrying out the functions in the Trace Evidence Section. Perform administrative and personnel management functions for staff. Observe employee's performance. Demonstrate and conduct work performance critiques. Provide feedback related to work performance. Provide advice and counsel to employees related to work matters. Ensure employees are trained and that they fully comply with safety regulations. Responsible for accomplishment of the work in the unit supervised through technical and administrative direction of the unit. Responsible for accomplishing non-supervisory work through state of the art expertise, providing rapid response and specialized analytical services.

TRAINING CADRES:

- Course Advisory Group (CAG) / Cadre Member, August 2009-present: IM214 Field Examination Using the Counterfeit Detector (CDx)
- Cadre Member, August 2010-present: IM216 Import Operations and Entry Review (overview course to the IM214)

SHORT COURSES / WORKSHOPS ATTENDED

- 2018 – FDA's 3D Printing In Medicine at the Center for Devices and Radiological Health (CDRH) by James Coburn and team (2 Days).
- 2011 - "Foster and Freeman Video Spectral Comparator with Hyper Spectral imaging, polarized light viewing, high magnifications and other imaging modules", by Foster and Freeman, Cincinnati, OH (1 Day).
- 2011 - "OpenLAB SDMS End User Training" course involved with the planning, designing, and implementation of FCC worksheet templates; course training received from Agilent Technologies using the "Agilent OL 3.3 ECM Administration Course Number R1643A at FCC in Cincinnati, Ohio, February 1 and 2, 2011 (2 Days).
- 2010 - "Mideo Systems Caseworks User and Administrator Training" course involved database creation onto imaging server, definition of IT/Network configuration requirements, workstation(s) definition of database security, case folder/fieldset design, administrator and user profile creation, security templates, utilities, and archiving; course training received from Travis Larkin Mideo Systems at FCC in Cincinnati, Ohio, March, 2010 (2 Days).
- 2009 - "IFM System InfiniteFocus G4 – 3D Imaging User and Administrator Training" course involved controlling the optical non-contact surface measurement 6-place nosepiece motorized, suspensioned xy-stage, digital co-axial illumination, and the use of the 3D surface analysis software for visualization and analysis including EN/ISO roughness and waviness measurements; course training received from Brian Wright BrookAnco Inc. at FCC in Cincinnati, Ohio, November, 2009 (1 Week).
- 2009 - "Pharmaceutical Tablet Technology" course involved with the design, formulation, manufacture, quality control and quality assurance of pharmaceutical tablets at Natoli Training Facility in St. Charles/St. Louis, MO August 18-20, 2009 (1 Week).
- 2006 - "Forensic Science Institute Of Ohio Toolmark" Course, FSIO/ATF Toolmark Workshop, Hamilton County Coroner's Lab, 3159 Eden Ave., Cincinnati, Ohio 45211 (1 week)
- 2006 - "Orientation to the Graphics Arts Seminar", Rochester Institute of Technology, Industry

- Education Programs, 67 Lomb Memorial Drive, Rochester, NY 14623-5603 (1 week)
- 2006 - Dayton Ohio Crime Lab Toolmark Identification Training (1 week)
- 2005 - “Printing Process Identification and Image Analysis for Forensic Document Examiners Seminar”, Rochester Institute of Technology, Industry Education Programs, 67 Lomb Memorial Drive, Rochester, NY 14623-5603 (1 week)
- 2005 - “Color Without Limits” seminar given by Graphic Intelligent Agency (GIA), Cincinnati, OH (1 Day)
- 2004 - Miami Crime Regional Laboratory Tool Mark Examination Training Course (2 weeks)
- 2003 - FEI QuantaTM Environmental Scanning Electron Microscopy Training Course Boston, Massachusetts (4 days).
- 2000 - John E. Reid and Associates “The Reid Technique of Interview and Interrogation”, Hamilton County Coroner’s Laboratory, Cincinnati, OH (2 Weeks).
- 2000 - Computer Programming in Image Analysis with Auto Pro, Media Cybernetics, L.P., in Silver Spring, MD (2.5 days)
- 2000 - FDA certificate for Successfully Completing the Quality Systems and Audit Workshop, Bethesda, Maryland (1 Weeks)
- 2000 - Food and Drug Law, Bethesda, MD (1 week)
- 2000 - FDA Evidence Development, Bethesda, Maryland (1 Week)
- 2000 - FDA Investigative Interviewing Techniques Course, Bethesda, Maryland (1 week)
- 1999 - Scanning Electron Microscopy Energy Dispersive X-Ray Spectroscopy Workshop in Forensic Science at the Midwestern Association of Forensic Scientists (MAFS) Workshop, Cincinnati, OH. (3 days)
- 1999 - FBI Recognition on “Scanning Electron Microscopy in Forensic Science” (1 week)
- 1998 - Expert Witness Testimony Workshop, Cincinnati, OH. (3 days)
- 1998 - Forensic Geology, Forensic Science Institute of Ohio, Columbus, OH. (1 day)
- 1996 - The George Washington University School of Medicine and Health Sciences Center for Microscopy and Image Analysis, Nicola Ranieri, has satisfactorily completed a course entitled Protocols in: Confocal Microscopy, Image Analysis and Immunocytochemistry, Washington, DC. (4 days)
- 1995 - North Carolina State University, Computer-Assisted Image Analysis and Measurements, Raleigh, NC. (3 days)
- 1993 - FDA Law and Testimony Training, FDA, Cincinnati. OH. (1 day)
- 1992 - Chemical Hygiene Training, FDA, Cincinnati, OH. (1 day)
- 1992 - LEICA Stereoscan Training Course, Leica Inc., Deerfield, IL. (3 days)
- 1992 - Laboratory Procedures and Techniques for Chemists, FDA, Denver, Colorado. (2 weeks)

ADDITIONAL TRAINING RECEIVED

US Government Training Classes (through FDA)

Scientific Report Writing	•	Sexual Harassment - Non-Supervisory Personnel Stress
Management	•	LOTUS 1-2-3
MS Word	•	MS Outlook
MS Access	•	WordPerfect
Advanced WordPerfect	•	Basic Computer Language
EASE General Employee Training	•	Chemical Hygiene Training
Ethics Training	•	On-Line Information System Security Training
FACTS Training	•	Fire Extinguisher Training
QA & FCC Databases	•	FCC Sample Sealing Procedures
Security Training	•	Blood Borne Pathogens – Exposure Training
Sample Sealing and Worksheets	•	Cardiopulmonary Resuscitation (Red Cross)
Court Testimony	•	Back-To-Basics

Worksheet Training	•	Chemical Hygiene / Hazard Communication
WORD '97	•	Expert Witness Workshop
Investment in Excellence (FDA)	•	Defensive Driving Techniques
Ethics Training (FDA)	•	Scanning Electron Microscopy for Biological Sciences
Emergency Preparation / Hazardous Chemical / Bio-Hazard Spill		

- **Courses IM214 and IM216** – “Field Examination of Counterfeit Import Products and Packaging using the Counterfeit Detector (CDx)”, including the “Detection of suspected counterfeit packaging utilizing a hand held digital microscope and a hand held LED light source”, “Printing Process Determination” and “Basic Photography for ALS Analysis”
223 participants trained – 2007-Present (as of March 2017):
 - 201 Consumer Safety Officers (CSOs)/Consumer Safety Officer Supervisors (CSOS)/FDA Import Investigators
 - 16 OCI Special Agents
 - 4 Health Canada inspectors
 - 2 from Center for Drug Evaluation and Research (CDER)
 - 107 IM216 trained participants
- **Requested Customized / Special Trainings:**
 - **Tablet Press and Tablet Manufacturing Process:**
 - 2017 – Summer intern, college student Zane Smiddy - trained in tablet analysis – worked on advancing tablet manufacturing processes detection
 - **Detection of counterfeit anti-malarial drugs utilizing the Counterfeit Detector 3 Plus (CD3+), “Detection of suspected counterfeit packaging utilizing a hand held digital microscope and a hand held LED light source”, “Printing Process Determination” and “Basic Photography for ALS Analysis”**
287 participants in customized trainings 2006-Present (as of March 2017)
 - 98 individuals: investigators and chemists of the United States Pharmacopeia (USP) CePAT Investigators in Accra, Ghana, Africa; Lao Food and Drug Department (FDD) Investigators in South East Asia, Vientiane, Laos (Lao People’s Democratic Republic); scientists from the Centers for Disease Control and Prevention (CDC) in the Division of Parasitic Diseases; OCI Special Agents;
 - 15 FCC analysts on the detection of suspected counterfeit packaging utilizing a hand held digital microscope and a hand held light microscope for Active Pharmaceutical Ingredients (API) investigations assisted by FCC
 - Lehrbeauftragter Department für Medizinisch/Pharmazeutische Chemie Pharmazie-Zentrum (LDM/PCPZ) UZA, Vienna, Austria
 - Import Operation Investigators and Entry Reviewers training on examination of national and international API manufacturers API labels and documentation:
 - 38 at FDA Newark, New Jersey
 - 20 CSOs and FDA Investigators in Division of Import Operations Policies (DIOP) branch in Chi-DO
 - 37 at FDA San Juan, Puerto Rico
 - 17 at FDA International Mail Facility in Los Angeles, California
 - 2 Medicines and Healthcare Products Regulatory Agency (MHRA) investigators
 - 8 members of the International Laboratory Forum on Counterfeit Medicines (ILFCM)
 - 1 from the Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN)

- 1 CBP laboratory personnel
- 21 and 27 LOS-DO Imports and LAPD (Anti-Piracy Investigative Unit), and 5 Custom Border Patrol (CBP) agents; Counterfeit Detection Training in Los Angeles covered visual cues, the tool (CDx), and the micro world of printing
- 1 at LOS-DO, Albert Chang (CSO) on how to properly use the PDS for the IMF
- **Photo Documentation System (PDS) using the Mideo Systems Caseworks** - 2011-Present
 - LOS-DO Consumer Safety Officer as administrative user of the PDS
 - FCC analyst, as administrative user of the PDS system
 - All FCC analysts as users of PDS
 - FCC Intern – Kelsey DeWitt
 - Supervisor of Consumer Safety Officer (CSO) at FDA LOS-DO Import Operation
 - CSOs and FDA Investigators at International Mail Facility (IMF) Import Operation
 - OCI - Completed Mideo Templates for Tobacco Enforcement Program Mideo system and instructed on its use
- **Computer-Assisted 2D IA and 3D Profolometry and Measurements** – 2005- Present
 - TES analyst Frank Platek, on 3D profilometry
 - Lehrbeauftragter Department für Medizinisch/Pharmazeutische Chemie Pharmazie-Zentrum (LDM/PCPZ) UZA, Vienna, Austria
 - Forensic Science Center (FSC), Taipei City Police Department, Taipei, Taiwan, R.O.C
 - Forensic Scientist, Forensic Chemistry and Physics Laboratory, Health Sciences Authority (HSA), Singapore
 - FCC analysts and FCC Intern – Kelsey DeWitt
 - Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN)
- **Toolmark Microscopy/Macroscopy Analysis** - 2005-Present
 - FCC analyst on Rubber Stopper Puncture Analysis
 - Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN)
- **Color Measurement Spectrometer (hand-held and bench top) to accurately measure color of foods, beverages, powders, labels, pharmaceutical finished dosage forms, etc.** - 2006-Present
 - FCC analysts
- **Access Database Designing and Scripting Training** - 2009-Present
 - FCC analyst
 - Little Miami High School student

PATENTS ATTAINED

- USA Patents – two full and one pending:
 - **US Patent 1 – FULL PATENT:**
 - Patent issued and published in the Federal Registry: U.S. Patent No. 9,476,839 on October 25, 2016. On FDA record the U.S. Patent No. 9,476,839 is the file named: “US9476839B2.pdf”
 - Developed a hand held device for anti-counterfeiting. The device is currently being used by FDA investigators and OCI Special Agents.

- Title: A Hand Held Portable Device Based on Light Emitting Diodes (LEDs) as a Light Source for Use in the Detection of Counterfeit Pharmaceutical Drugs (claims the 1st version):
- Filed on March 31, 2009
- Analyst Reference No. E-206-2008/0-US-00
- Inventors: Nicola Ranieri et al.
- ABSTRACT OF THE DISCLOSURE: A hand-held device and method for detection of counterfeit pharmaceuticals. Counterfeit pharmaceuticals are detected by visual inspection upon exposing a genuine pharmaceutical and a corresponding suspected counterfeit pharmaceutical to one or more light sources having different wavelengths, and observing the differences in color and/or brightness between the suspected counterfeit and genuine pharmaceutical.
- Patent application submitted through National Institutes Of Health (NIH), Michael A. Shmilovich Sr. Licensing & Patenting Manager, 6011 Executive Blvd., Suite 323, Rockville, MD, 20852-3804
- Published in the Federal Registry on March 31, 2010

- US Patent 2 – FULL PATENT:
 - Patent issued and published in the Federal Registry: U.S. Patent No. 10,007,920 issued on June 26, 2018. On FDA record the issued U.S. Patent No. 10,007,920 is the file named: “US10007920.pdf”
 - Developed a multi-use hand held device for anti-counterfeiting, documents, currency, liquids, and other products. The device is currently patent pending.
 - Title: Device And Method For Detection Of Counterfeit Pharmaceuticals And/Or Other Packaging (claims the 2nd version):
 - Filed on December 7, 2012
 - Analyst Reference No. E-2013-002/US-03; 9531-98516-04
 - Inventors: Nicola Ranieri et al.
 - ABSTRACT OF THE DISCLOSURE: The device can be used in the detection of counterfeit pharmaceutical drugs, packaging and other forensic applications. The device has the potential to be used in a wide variety of other applications both in government and the private sector.
 - Patent application submitted through National Institutes Of Health (NIH), Michael A. Shmilovich Sr. Licensing & Patenting Manager, 6011 Executive Blvd., Suite 323, Rockville, MD, 20852-3804
 - Published in the Federal Registry on December 13, 2013

- US Patent 3 – Patent Pending:
 - Developed an enhanced multi-use hand held device for anti-counterfeiting, documents, currency, liquids, and other products. The device is currently in the patent pending phase.
 - Title: Device And Method For Detection Of Counterfeit Pharmaceuticals And/Or Other Packaging (claims the 3rd version):
 - U.S. Patent Application Serial No.: 621110,090- Filing Date: January 30, 2015
 - NIH Ref.: E-074-2015/0-US-01
 - Locke Lord Ref.: 97063P(47992) Immediate Lineage: N/A
 - Inventors: Nicola Ranieri et al.
 - Title: Device And Method For Detection Of Counterfeit Pharmaceuticals And/Or Other Packaging
 - ABSTRACT OF THE DISCLOSURE: The device can be used in the detection of counterfeit pharmaceutical drugs, packaging and other forensic applications.

The device has the potential to be used in a wide variety of other applications both in government and the private sector.

- Patent application submitted through National Institutes Of Health (NIH), Michael A. Shmilovich Sr. Licensing & Patenting Manager, 6011 Executive Blvd., Suite 323, Rockville, MD, 20852-3804
- US National Stage application through new Law Firm handling the CDx technologies Carsten Grellmann

○ Two Active Patents in Europe:

○ EU Patent 1 – Patent Cooperative Treaty (PCT)

- Immediate Lineage: US Provisional Patent Application No. 61/165,395
- EP Patent Application No. 107284765.5 filed March 31, 2010
- International Patent Application No. PCT/US2010/029502
- NIH Ref.: E-206-20080/0-PCT-03
- EAPD Ref.: 85065WO(47992)
- Inventors: Nicola Ranieri et al.
- PCT Patent application submitted through Michael A. Shmilovich Sr., Licensing & Patenting Manager, National Institutes Of Health, 6011 Executive Blvd., Suite 323, Rockville, MD, 20852-3804
- International Patent Application submitted on October 21, 2010 under the Patent Cooperation Treaty (PCT).
- International Patent Application published on February 8, 2012 notification of the bibliography data of the patent is published in the European Patent Bulletin.

○ EU Patent 2 – Patent Cooperative Treaty (PCT)

- Immediate Lineage: US Provisional Patent Application No. 61/734,829
- EP Patent Application No. 201110915.2 filed December 7, 2012
- International Patent Application No. PCT/US20131073526
- NIH Ref.: E-005-201310/0-PCT-02
- EAPD Ref.: 91545WO(47992)
- Inventors: Nicola Ranieri et al.
- PCT Patent application submitted through Michael A. Shmilovich Sr., Licensing & Patenting Manager, National Institutes Of Health, 6011 Executive Blvd., Suite 323, Rockville, MD, 20852-3804
- International Patent Application submitted on December 6, 2013 under the Patent Cooperation Treaty (PCT).
- International Patent Application published on June 12, 2014 (12.06.2014) under No. WO 2014/OU9406 notification of the bibliography data of the patent is published in the European Patent Bulletin.

PUBLICATIONS:

- “Assessment of the effectiveness of the CD3+ tool to detect counterfeit and substandard anti-malarials”; Batson JS., Bempong DK., Lukulay PH., Ranieri N., Satzger RD., Verbois L.; Malar J. 2016 Feb 25;15:119. doi: 10.1186/s12936-016-1180-2, 2/2016
<https://www.ncbi.nlm.nih.gov/pubmed/26917250>
- “Analysis of Counterfeit FDA-Regulated Products at the Forensic Chemistry Center: Rapid Visual and Chemical Screening Procedures Inside and Outside of the Laboratory”; Adam Lanzarotta, **Nicola Ranieri**, Douglas Albright, Mark Witkowski, JaCinta Batson and Moseley Fulcher; American Pharmaceutical Review, 2015, 18, 24-29

- “Integration of Novel Low-cost Colorimetric, Laser Photometric and Visual Fluorescent Techniques for Rapid Identification of Falsified Medicines in Resource-poor Areas: Application to Artemether-lumefantrine” American Journal of Tropical Medicine and Hygiene (AJTMH); Green D. Michael, Dana M. Hostetler, Henry Nettey, Isabel Swamidoss, **Nicola Ranieri**, Paul N. Newton; Accepted for publication in The American Journal of Tropical Medicine & Hygiene. February 2015
- “Effectiveness and Versatility of Paper-based Test Cards for Screening of Pharmaceutical Dosage Forms” Public Library Of Science Online (PLOS ONE); Abigail Weaver¹, Sara Andria², **Nicola Ranieri**², Mark Witkowski², Cheryl Flurer², Marya Lieberman¹; ¹Department of Chemistry and Biochemistry, University of Notre Dame, Notre Dame, IN, 46556; ²US Food and Drug Administration, Forensic Chemistry Center, 6751 Steger Drive, Cincinnati, OH, 45237; review status by the journal’s editorial board, 2014
- “Evaluation of a New Handheld Instrument for the Detection of Counterfeit Artesunate by Visual Fluorescence Comparison” American Journal of Tropical Medicine and Hygiene (AJTMH), 91(5), 2014, pp. 920–924; **Nicola Ranieri**¹, Patricia Tabernero², Michael D. Green³, Leigh Verbois⁴, James Herrington⁵, Eric Sampson³, R. Duane Satzger¹, Chindaphone Phonlavong⁶, Khamxay Thao⁷, Paul N. Newton^{8, 9}, Mark R. Witkowski¹; ¹US Food and Drug Administration, Forensic Chemistry Center, 6751 Steger Drive, Cincinnati, OH, 45237, USA; ²Worldwide Antimalarial Resistance Network (WWARN), Nuffield Department of Clinical Medicine, University of Oxford, Oxford, United Kingdom; ³Center for Disease Control, Division of Parasitic Diseases and Malaria, Atlanta, Georgia, USA; ⁴U.S. Food and Drug Administration, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Silver Springs, MD, 20993, USA; ⁵National Institute of Health, Fogarty International Center, Bethesda, MD, 20892, USA; ⁶Bureau of Food and Drug Inspection (BFDI), Ministry of Health, Government of the Lao PDR; ⁷Food and Drug Quality Control Centre (FDQCC), Ministry of Health, Government of the Lao PDR; ⁸Centre for Tropical Medicine, Nuffield Department of Clinical Medicine, Churchill Hospital, University of Oxford, Oxford, United Kingdom; ⁹Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit (LOMWRU), Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit (LOMWRU), Microbiology Laboratory, Mahosot Hospital, Vientiane, Lao PDR; AJTMH. 2014; 91, 920-924
- US Food and Drug Administration, 2013. CD-3: “A New Tool in FDA’s Fight Against Counterfeit Products. Available” at: <http://www.youtube.com/watch?v=mfYUkiKAJvA>. Accessed September 16, 2014
- "Application of 2D and 3D Optical Microscopy in the Examination of Suspect Counterfeit Pharmaceutical Tablets" manuscript in the Proceedings of the M&M 2010 International meeting. Microscopy and Microanalysis 2010, Portland, OR; S. Frank Platek; **Nicola Ranieri**, Douglas C Albright and Mark R. Witkowski, 2010
- “A Method for the Determination of Syringe Needle Punctures in Rubber Stoppers Using Stereoscopic Light Microscopy”; J Forensic Sci, Vol. 47(5), pp. 986-992; S. Frank Platek, Mark A. Keisler, **Nicola Ranieri**, Todd W. Reynolds, and John B. Crowe, 2002
- “Scanning Electron Microscopy Determination of String Mozzarella Cheese in Gastric Contents”. J Forensic Sci, Vol. 46(1), pp. 131-134; S. F. Platek, J.B. Crowe, **N. Ranieri** and K.A. Wolnik, 2001

- "Supermarket Tampering: Cocaine in Syringes and in Fruit", J Forensic Sci, Vol. 46(1), pp. 144-146; Tomlinson, J.A., Crowe, J.B., **Ranieri, N.**, Kindig, J.P., and Platek, S.F., 2001
- "Malicious Tampering of Food Products". Presented at the Twelfth International Meeting of SCANNING 2000, Food Contaminants Short Course, San Antonio, TX; S.F.Platek, J.B. Crowe and **N. Ranieri**, (extended abstract) 2000
- "Classification of Puncture Holes in Plastic Bottles by Light and Scanning Electron Microscopy: A Preliminary Study" "Presented at the Twelfth International Meeting of SCANNING 2000, Food Contaminants Short Course; S.F.Platek, **N. Ranieri**, J.B. Crowe and Karen A. Wolnik; San Antonio, TX, (extended abstract) 2000
- A False Report of Product Tampering Involving a Rodent and Soft Drink Can: Light Microscopy, Image Analysis and Scanning Electron Microscopy/Energy Dispersive X-ray Analysis. J Forensic Sci, Vol. 42(6), pp. 1169-1173; S. Frank Platek, **Nicola Ranieri** and Karen A. Wolnik, 1997
- Forensic Microscopy Analysis of Unique Cases Related to Food and Pharmaceutical Tampering and Counterfeiting. S.F. Platek, J.B. Crowe, **N. Ranieri** and K.A. Wolnik. SCANNING, Vol. 18(3), pp. 175-176, 1996
- The Mouse That Roared - A Case of Reported False Product Tampering. Proceedings of the Annual Meeting of the American Academy of Forensic Sciences 48th; S. F. Platek, **N. Ranieri** and K. A. Wolnik, 1996
- Food and Drug Administration Proposed Rule Analysis Regarding FDA's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco; S.F. Platek, **Nicola Ranieri** and Karen A. Wolnik. Notice; "Industry Manipulation and Control of Nicotine in Smokeless Tobacco", Federal Register, Vol. 60(155), pp. 1995, 273-288. (Research and analytical results published therein), 1995
- Forensic Scanning Electron Microscopy/Energy Dispersive X-ray Analysis Related to Food Product Tampering and Pharmaceutical Counterfeiting. Published in the proceedings of "SCANNING", Vol. 17, Supplement V, pp. 47-48; S.F. Platek, **Nicola Ranieri** and Karen A. Wolnik, 1995
- Analysis of Suspect Food and Beverage Product Tampering and Pharmaceutical Counterfeiting by Light Microscopy and SEM/EDX Analysis. Proceedings of the Great Lakes Microscopy Conference 1995, GLeMA'95; S.F. Platek, **N. Ranieri** and K.A. Wolnik, 1995

CONFERENCES / SEMINARS / MEETINGS

- **Quality of Medical Products and Public Health – Oxford University, United Kingdom**
"Quality of Medicines and Packaging"; **Nicola Ranieri**, and JaCinta Batson; Teach/Lecture a course as a faculty member, on counterfeit determination and hand-held scanning techniques tools used for the detection of counterfeit pharmaceutical products; course taught at the Department for Continuing Education, Oxford University, Wolfson College, in Oxford, United Kingdom; September 17-21, 2018 (Invited).
- **Asia-Pacific Economic Cooperation (APEC) - United States Pharmacopeia (USP) Training Center**
"Detection and Screening Technologies"; USP-APEC Regulatory Harmonization Steering Committee (RHSC) Center of Excellence (CoE) for Product Quality & Supply Chain Pilot Program:

- **Microscopy and Microanalysis (M&M)**

“Application of 3D and 2D Imaging Techniques in the Examination of Suspect Tablets for the Detection of Counterfeit FDA-Regulated Products”; **Nicola Ranieri**, S. Frank Platek, Douglas Albright, and JaCinta S. Batson; presented at the 2016 Microscopy & Microanalysis (M&M) meeting in Columbus, Ohio; July 27, 2016 (Invited)

- **Microscopy and Microanalysis (M&M)**

“Applications of the FDA’s Counterfeit Detection Device (CD3+) to the Examination of Suspect Counterfeit Pharmaceutical Tablets and Packaging”; S. Frank Platek, **Nicola Ranieri** and JaCinta Batson; presented at the 2016 Microscopy & Microanalysis (M&M) meeting in Columbus, Ohio; July 27, 2016

- **American Academy of Forensic Sciences**

“X-Ray Powder Diffraction (XRPD) Method Development and Validation for the Identification of Counterfeit Pharmaceuticals”; M.R. Witkowski, **N. Ranieri**, J. Batson, L.L. Richards-Waugh, and K.M. DeWitt; presented at the 2016 American Academy of Forensic Sciences in Las Vegas, NV; February 2016

- **American Association of Pharmaceutical Scientists (AAPS)**

“CD3 Development and Application in the Fight against Counterfeit Products”; **Nicola Ranieri**, Mark Witkowski, JaCinta Batson, Cheryl Flurer, Duane Satzger, and Leigh Verbois; presented at the 2015 meeting American Association of Pharmaceutical Scientists (AAPS), Orange County Convention Center, Orlando, Florida; October 29, 2015 (Invited)

- **Marshall University**

“X-Ray Powder Diffraction Method Development and Validation for the Identification of Counterfeit Pharmaceuticals” Kelsey DeWitt, JaCinta Batson, M.S., Mark Witkowski, Ph.D., **Nicola Ranieri**, Lauren Richards-Waugh, Ph.D. Presented for an Intern-Fellowship at FDA and graded for a graduate course at the Marshall University in Huntington, West Virginia; August 2015

- **LOS-DO Imports, LAPD (Anti-Piracy Investigative Unit) and Custom Border Patrol (CBP)**

“Printing Process Determination” by Nicola Ranieri and Douglas Albright; Counterfeit Detection Training in Los Angeles to LOS-DO Imports, LAPD (Anti-Piracy Investigative Unit), and Custom Border Patrol (CBP) agents; training covered visual cues, the tool (CDx), and the micro world of printing; July 1, 2015

- **Investigative Consultants (IC)**

“Detecting Counterfeit Pharmaceutical Products by the Food and Drug Administration’s Forensic Chemistry Center (FCC) and FDA Fields using hand-held devices”; **Nicola Ranieri**, Adam Lanzarotta, Doug Albright, and Mark Witkowski; Los Angeles at Investigative Consultants (IC), an anti-counterfeiting training organization for various law enforcement agencies including LAPD and LOS-DO; June 29, 2015 (Invited)

- **FDA Science Forum 2015**

“Screening for Counterfeit Pharmaceutical Products using the CDx Device in Ultraviolet, Visible, and Infrared modes for Field and Laboratory use”; **Nicola Ranieri**, Mark Witkowski, and Duane Satzger; Presented at the FDA Science Forum 2015, FDA White Oak Bldg., Washington DC; May 28, 2015 (Invited)

- **SPIE DSS 2015 - Defense, Security and Sensing**

“Advancing Public Health through Regulatory Science: FDA’s development of a counterfeit detection tool CDx”; Nicola Ranieri, Leigh Verbois PhD, JaCinta Batson, MS, MBA, Mark Witkowski PhD, Duane Satzger PhD, and Cheryl Flurer PhD. Presented at SPIE DSS 2015 - Defense, Security and Sensing, Baltimore, Maryland; April 21, 2015

- **Microscopy Society of the Ohio River Valley**

“Applications of Light and Electron Microscopy to Forensic Casework at the US FDA”; S. Frank Platek, MS, Douglas C. Albright, JaCinta S. Batson, MS, MBA, John B. Crowe, Moseley Fulcher, Stefanie L. Heckman, MSFS, Adam C. Lanzarotta, PhD, **Nicola Ranieri**, Mark R. Witkowski, PhD; Presented at the 2015 Spring Meeting of the Microscopy Society of the Ohio River Valley; April 15, 2015

- **American Association of Pharmaceutical Scientists (AAPS)**

“Analysis of Counterfeit FDA-Regulated Products at the Forensic Chemistry Center: Rapid Visual and Chemical Screening Procedures Inside and Outside of the Laboratory”; Adam Lanzarotta, **Nicola Ranieri**, Douglas Albright, Mark Witkowski, JaCinta Batson, and Moseley Fulcher; Accepted for publication in American Association of Pharmaceutical Scientists (AAPS); April 2015

- **FDA Technology Transfer Program (Office of the Chief Scientist)**

“Novel Technology Innovations and Submission for Patents”; Continued Education (CE) workshop training classes; **Nicola Ranieri**; Alice Y. Welch, Director; William Ronnenberg, Deputy Director; Marc Allard; Ilko K. Ilev; Surender Khurana; FDA White Oak campus; March 24, 2015 (Invited)

- **FDA Technology Transfer Program (Office of Technology Transfer)**

“Novel Technology Innovations and Submission for Patents”. **Nicola Ranieri**. Continued Education (CE) workshop training classes. FDA White Oak Campus. March 24, 2015 (Invited)

- **Eastern Analytical Symposium**

“Analysis of Counterfeit Products by the FDA Forensic Chemistry Center”. Adam C. Lanzarotta and **Nicola Ranieri**. Somerset, NJ, November 2014, abstract number 166

- **US Patent & Trademark Office (USPTO) Global Intellectual Property Academy (GIPA)**

“Assisting the Anti-Counterfeiting Detection Task Force using the FDA’s Counterfeiting Detection Version 3*Plus* Device”. **Nicola Ranieri** at “Combating the Trafficking of Fraudulent Medicines in Sub-Saharan Africa” training seminar attended by health/drug regulators and law enforcement officials from Angola, Botswana, Mozambique, Namibia, South Africa, Tanzania, and Zambia, June 25, 2014 (Invited)

- **Embassy of France – World Anti-Counterfeiting Day Seminar**

“Detection of counterfeit anti-malarial drugs utilizing the Counterfeit Detector 3 *Plus* (CD3+)”. **Nicola Ranieri** at the “World Anti-Counterfeiting Day - Trafficking and Counterfeiting of Medicines: A Toolkit for Investigators” Seminar, Organized by the French Law Enforcement Attachés (Police, Customs, Justice, IPR) at the, 4101 Reservoir Road, N.W. Washington, D.C., May 28, 2014 (Invited)

- **American Society of Tropical Medicine and Hygiene (ASTMH)**

“Development of Paper-based Pharmaceutical Screening Tools”. Abigail Weaver, Sara Andria^{*}, **Nicola Ranieri**^{*}, Mark Witkowski^{*}, Cheryl Flurer^{*}, Sarah Halweg, Marya Lieberman, and Holly Goodson; University of Notre Dame, Notre Dame, Indiana; ^{*}US Food and Drug Administration, November 11, 2013

- **USG Stakeholder Meeting**

"Anti-Malarial use of the Counterfeit Detection device version 3 (CD3)". **Nicola Ranieri** and FCC Lab Director Dr. Duane Satzger at the requested by Valdez, Mary Lou, USAID- Global Health, Washington DC, February 28, 2013 (Invited)

- **Skoll Foundation Meeting**
"Counterfeit Anti-Malarial Drugs Detection using the Counterfeit Detection device version 3 (CD3)". **Nicola Ranieri** and FCC Lab Director Dr. Duane Satzger to the Mark Smolinski's Skoll Foundation meeting, Discussion of potential collaboration/support with FCC, Rockville, MD, December 13, 2012 (Invited)
- **FCC Anti-Counterfeiting Meeting**
"Field Examination of Counterfeit Import Products and Packaging using the Counterfeit Detector 3 (CD3)". **Nicola Ranieri**, to Center for Drug Evaluation and Research (CDER) Research Chemist John F. Kauffman, Ph.D., and DHHS FDA Deputy Director, India Office Albinus M. D'Sa, Ph.D., September 26, 2012 (Invited)
- **FDA Science Writers Symposium**
"FDA Unveils A New Device That Detects Counterfeit Drugs" and a "Field Portable Instrumentation" at the FDA Science Writers Symposium; Dr. Margaret A. Hamburg, Commissioner of Food and Drugs unveiled to the American people, as well as to the World in front of numerous news cameras, FDA's new tool used to fight against counterfeiters of pharmaceuticals finished dosage form; **Nicola Ranieri** and FCC Lab Director Dr. Duane Satzger presented and gave a live demo of the device's capabilities while being recorded by the news media, September 10, 2012 (Invited)
- **Deputy Commissioner for Globalization Autor, Deborah Meeting**
"Introduction to the suspected counterfeit drug detector, CD3 handheld device". **Nicola Ranieri** and FCC Lab Director Dr. Duane Satzger to Deputy Commissioner for Globalization Autor, Deborah, and Eric Sampson, Leigh Verbois, Senior Regulatory Policy Jennifer Devine on Counterfeit Medicines presented in the White Oak Building Rockville, Maryland; a one day CD3 discussions, 2012 (Invited)
- **SSFFC Meeting**
"Detection of suspected counterfeit drugs and packaging utilizing the CD3 handheld device". **Nicola Ranieri** and FCC Lab Director Dr. Duane Satzger at OCI Headquarters on Counterfeit Medicines presented in Silver Spring, Maryland; a one day CD3 overview, August 27, 2012 (Invited)
- **Lao Food and Drug Department (FDD) Deputy Director Meeting**
South East Asia, Vientiane, Laos (Lao People's Democratic Republic) Dr. Lamphone Syhakhang Pharmacist Ph.D., Deputy Director of the Lao Food and Drug Department (FDD) and twelve FDD management members. "Field Examination of Counterfeit Import Products and Packaging using the Counterfeit Detector 3 (CD3)". **Nicola Ranieri** (FDA), Eric Sampson (CDC), Leigh Verbois (FDA), Mike Greene (CDC), and Jim Herrington (NIH); July 19, 2012 (Invited)
- **Lao FDD Deputy Head Drug Control Division Meeting**
South East Asia, Vientiane, Laos (Lao People's Democratic Republic) Dr. Sivong Sengaloundeth, Pharmacist Ph.D., Deputy Director General, and Bounxou Keohavong, MMA, Deputy Head Drug Control Division. "Field Examination of Counterfeit Import Products and Packaging using the Counterfeit Detector 3 (CD3)". **Nicola Ranieri** (FDA), Eric Sampson (CDC), Leigh Verbois (FDA), Mike Greene (CDC), and Jim Herrington (NIH), July 17, 2012 (Invited)
- **Los Angeles International Mail Facility (IMF) Meeting**

IMF in Torrence, CA and at the FDA building in San Pedro, CA presented "Photo Documentation and Administration by use of Mideo Systems Caseworks for the IMFs"; **Nicola Ranieri**, September 27, 2011 (Invited)

- **SPIE-Defense, Security and Sensing Meeting**
"Scanning Microscopies in Forensic Science: Classic and New Applications" S.F. Platek, M.R. Witkowski, **N. Ranieri**, J.B. Crowe, A.C. Lanzarotta, and D.C. Albright, Orlando, FL; May 2011
- **Eli Lilly Division of Global Security and Quality Management Meeting**
"Field Examination of Counterfeit Import Products and Packaging using the Counterfeit Detector 3 (CD3)". **Nicola Ranieri** to Gerald Miller, Jeffry Denault, Ph.D., and Jacqueline Larew, Ph.D., June 2, 2011 (Invited)
- **California Customs Border Patrol (CBP) Meeting**
"Examination of Counterfeit Passports and Identification Cards using the Counterfeit Detector 3 (CD3)". **Nicola Ranieri** at the Los Angeles CBP to the Acting Area Port Director Sergio Espinoza, Assistant Port Director/Director of CEE Ann Maricich, Assistant Director Field Ops for Border Security Loretta Sanchez, Program Manager Cheryl Davis, Supervisory Import Specialist Jorge Garcia, Section Chief Anthony Owens, Section Chief Thomas Reis, Section Chief Daniel Gamboa, and Gordon Chu LOS-DO Imports, April 28, 2011 (Invited)
- **American Academy Forensic Sciences (AAFS)**
"Unique Evidence and Examination in Methadone Suspected Death" Caroline Machal Kelley, B.S.*, **Nicola Ranieri**, B.S., Rick A. Flurer, Ph.D., Samuel R. Gratz, Ph.D., and Thomas W. Brueggemeyer, Ph.D., March 2011
- **American Academy of Forensic Science (AAFS) Annual Meeting**
"Unique Evidence and Examination in Methadone Suspected Death" Caroline Machal Kelley, B.S.*, **Nicola Ranieri**, B.S., Rick A. Flurer, Ph.D., Samuel R. Gratz, Ph.D., and Thomas W. Brueggemeyer, Ph.D., in Chicago, IL, February 21-26, 2011
- **International Ion Chromatography Symposium**
"Forensic Analysis of Toothpaste using Ion Chromatography" C.O. Dasenbrock, J. Brzezinski, **N. Ranieri**, K. Mulligan, J. Litzau, and M. Fulcher, in Cincinnati, OH; September 2010
- **FDA Headquarter Directors Meeting**
"Counterfeit Detector 3 (CD3)". **Nicola Ranieri** and Mark Witkowski to ORO Directors, ORA HQ DIOP Directors, ACRA HQ Directors, OE Directors, and CDER representatives, at FDA HQ, September 9, 2010 (Invited)
- **Pharmaceutical Applications Symposium Microscopy and Microanalysis**
"Application of 2D and 3D Optical Microscopy in the Examination of Suspect Counterfeit Pharmaceutical Tablets", Portland, OR; S. Frank Platek; **Nicola Ranieri**, Douglas C Albright and Mark R. Witkowski, August 2, 2010
- **Federation of Analytical Chemistry and Spectroscopy Societies (FACSS)** "Applications of Image Analysis on Pharmaceutical Products" **Nicola Ranieri**, and Douglas Albright; Forensic Applications of Image Analysis, and Forensic Imaging. 36th FACSS in Louisville, KY, March 9-10, 2010 (Invited)
- **Federation of Analytical Chemistry and Spectroscopy Societies (FACSS)**
"Trace Examination Techniques and Their Use in Pharmaceutical Forensics". Mark Witkowski,

Douglas Albright, JaCinta Batson, John Crowe, Moseley Fulcher, Adam Lanzarotta, Sara Adrian, Frank Platek, **Nicola Ranieri**. Symposium of Pharmaceutical Forensics by Forensic Molecular Spectroscopy Microscopy, 36th FACSS in Louisville, KY; October 20, 2009

- **Microscopy Society of America**
"Applications of Microscopy and Microanalysis in US FDA Forensic Cases" S. Frank Platek, John B. Crowe, **Nicola Ranieri** and Mark Witkowski presented in the Forensic Science Symposium at Microscopy and Microanalysis 2009, in Richmond, VA; July 29, 2009
- **Indiana Microscopy Society**
"Light and Scanning Electron Microscopy Applications and Research in Forensic Science at the US FDA's Forensic Chemistry Center" S. Frank Platek, **Nicola Ranieri** and John B. Crowe. Spring Meeting, Ball State University, Muncie, IN; March 27, 2009
- **International Laboratory Forum (ILF) Counterfeit Meeting**
"Detection of suspected counterfeit drugs and packaging utilizing the Counterfeit Detector 1 (CD1) hand held device". **Nicola Ranieri** and Mark Witkowski, on Counterfeit Medicines, in Boulder, Co., May 24, 2008 (Invited)
- **Drug Enforcement Administration Special Testing Laboratory (DEA) Meeting** "Belize Punches and Tablets Analysis". **Nicola Ranieri**, Frank S. Platek, and John B. Crowe, in Dulles, VA, scientific collaboration meeting, May 5-6, 2009 (Invited)
- **International Federation for Process Analytical Chemistry (IFPAC)**
"Categorization of Excipient Formulations in Counterfeit Pharmaceutical Products using Spectral Imaging/Mapping" Thomas W. Brueggemeyer, Mark R. Witkowski, Adam C. Lanzarotta, **Nicola Ranieri**, Baltimore, MD, January, 2009
- **College of Veterinary Medicine**
"Light and SEM Applications and Research in Forensic Science at the US FDA's Forensic Chemistry Center". S. Frank Platek, **Nicola Ranieri** and John B. Crowe. Presented to the Central States Microscopy and Microanalysis Society Meeting, Missouri University, Columbia, MO; April 25, 2008
- **Pittsburgh Conference in New Orleans**
"The Use of FT-IR, Raman Spectroscopy and SEM-EDX Toward the Analysis of Pharmaceutical Adhesive Labels" Adam C. Lanzarotta, **Nicola Ranieri**, Mark R. Witkowski, Andre J. Sommer. Presented to the Forensic Session: The Detection and Sourcing of Counterfeit Pharmaceuticals and Illicit Drugs, March 5, 2008
- **Biomedical Advanced Research and Development Authority (BARDA), and the Office of the Assistant Secretary for Preparedness and Response (ASPR) Meeting**
"FDA/FCC Anti-Counterfeiting". **Nicola Ranieri** and Mark Witkowski for Antivirals Pandemic Influenza Preparedness to the directors BARDA, ASPR, and the U.S. Department of Health and Human Services (DHHS), including Dial-in Participation by CDC and NIH; Washington, D.C., December 6, 2007 (Invited)
- **Microscopy Society of Northern Ohio**
"Forensic Microscopy Case Studies from the US FDA's Forensic Chemistry Center". S. Frank Platek, **Nicola Ranieri** and John B. Crowe, Cleveland, OH; March 15, 2007

- **FCC Laboratory Monthly Meeting**
“Applications of Image Analysis”. **Nicola Ranieri**, Cincinnati Ohio, March 14, 2007
(Invited)
- **Pittsburgh Conference**
“Applications of image analysis in forensic science”. **Nicola Ranieri** in the Forensic Session: The Detection and Sourcing of Counterfeit Pharmaceuticals and Illicit Drugs at the 2007 Pittsburgh Conference in Chicago Illinois, February 25, 2007 – March 01, 2007 (Invited)
- **WV State Police at Marshall University**
“Forensic Microscopy Case Studies from the US FDA's Forensic Chemistry Center” S. Frank Platek, John b. Crowe and **Nicola Ranieri**, to the Forensic Science Program and local law enforcement, November 3, 2006
- **International Ion Chromatography Symposium**
“The Use of Carbohydrate Profiling in the Investigation of Misbranded Infant Formula Using High Performance Anion Exchange Chromatography – Pulsed Amperometric Detection (HPAEC-PAD)”. David S. Jackson, **Nicola Ranieri**, and Catherine O. Dasenbrock, September 2006, Pittsburgh, Pa; September 2006
- **FDA Science Forum**
“Forensic Chemistry Center: Solutions to Current Forensic Challenges using Multiple Analytical Approaches”. R.A. Flurer, S.R. Gratz, **N. Ranieri**, M.R. Witkowski, T.Y. Yi, and R.D. Satzger, Washington, D.C., April 2006
- **Pittsburgh Conference Orlando**
“The Role of Adhesive and Label Chemical Analysis in Cases of Suspected Counterfeit and Diverted Products”. M.R. Witkowski, J. Crowe, **N. Ranieri**, A. Lanzarotta, F. Platek, J. Raezer, and J. Batson, Florida, March 2006
- **Particle Workshop National Institute of Standards and Technology Gaithersburg** “Particle Analysis in Forensic Science”. S.F. Platek, J.B. Crowe, and **N. Ranieri**, Maryland, March 2006
- **University of Rhode Island Chemistry Department, Sensors and Surfaces Technology Partnership and the Rhode Island State Crime Laboratory**
“Forensic Case Studies from the US FDA's Forensic Chemistry Center”. S. Frank Platek, John B. Crowe, Nicola Ranieri and Mark Witkowski, November 18, 2005
- **AAFS New Orleans**
“Poking Holes in the Suspect's Story: An Overview of Pharmaceutical Theft and Tampering Analyses” A.S. Mohrhaus, H.A. McCauley, **N. Ranieri**, and J.R. Urban, Louisiana, February 2005
- **Pittsburgh Conference Orlando (Poster)**
“Identification of Counterfeit Product Labeling Using Fourier Transform Infrared Spectroscopy” Jill Loeliger, Mark Witkowski, and Nicola Ranieri, Orlando, FL, March 9-14, 2003
- **The Fifteenth International Meeting of Modern Microscopy SCANNING 2003** “Detection of counterfeit product labels using Low Vacuum Scanning Electron Microscopy”. **Nicola Ranieri**, S.F. Platek, and J.B. Crowe, Poster, San Diego, CA, May 3-5,

- **FDA Science Forum**
“Detection of Counterfeit Finished Dosage Pharmaceuticals Using Multiple Analytical Techniques: An Example” C.L. Flurer, M.B. Jones, B.S. Barnes, J.B. Crowe, J.R. Loeliger, D.F. Crockett, **N. Ranieri**, M.R. Witkowski, R.D. Satzger and K.A. Wolnik, Washington, D.C. February 2002
- **Northern Kentucky University**
“Classification of Puncture Holes by Light and Scanning Electron Microscopy”. S.F. Platek, **Nicola Ranieri**, J.B. Crowe, Fall Meeting of Beta Beta Beta Biological Honor Society, Highland Heights, KY; November 1, 2001 (Invited)
- **FDA Science Forum - “Science Across the Boundaries” (Poster)**
“Classification of Puncture Holes in Plastic Bottles by Light and Scanning Electron Microscopy”. S.F. Platek, **N. Ranieri**, J.B. Crowe and Karen A. Wolnik, Washington, D.C., February 15-16, 2001
- **FDA Science Forum**
“Classification of Puncture Holes by Light and Scanning Electron Microscopy” S.F. Platek, **N. Ranieri**, J. B. Crowe, Washington D.C., February 15-16, 2001
- **Twelfth International Meeting of SCANNING**
“Classification of Puncture Holes in Plastic Bottles by Light and Scanning Electron Microscopy: A Preliminary Study”. S.F. Platek, **N. Ranieri**, J.B. Crowe and Karen A. Wolnik, Applications of Scanning Microscopy in Forensic Science Symposium, San Antonio, TX, May 10-11, 2000
- **Twelfth International Meeting of SCANNING**
“Malicious Tampering of Food Products”. S.F. Platek, J.B. Crowe and **N. Ranieri**, Food Contaminants Short Course, San Antonio, TX, May 9, 2000
- **INTER/MICRO-97**
“Metal Corrosion Analysis by SEM/EDX Related to Carbonated Beverage Tampering”. S.F. Platek, **N. Ranieri**, J.B. Crowe and K.A. Wolnik, Chicago, IL, July 21-24, 1997
- **48th Annual Meeting of the American Academy of Forensic Sciences**
“Microscopic Evidence of Ephedrine HCl; Identifying Sources of Manufacturers”. J.B. Crowe, S. Frank Platek, **Nicola Ranieri**, Douglas T. Heitkemper and Karen A. Wolnik, Nashville, TN February 22, 1996
- **48th Annual Meeting of the American Academy of Forensic Sciences**
“The Mouse That Roared - A Case of Reported False Product Tampering”. S. F. Platek, **N. Ranieri** and K. A. Wolnik, Nashville, TN, February 22, 1996
- **Seventh International Meeting of SCANNING**
“Forensic Microscopy Analysis of Unique Cases Related to Food and Pharmaceutical Tampering and Counterfeiting”. S.F. Platek, J.B. Crowe, **N. Ranieri** and K.A. Wolnik, Monterey, CA, April 11, 1996
- **Eighth International Meeting of SCANNING**

"Multiple Microscopy Analysis of Trace Evidence and Research Related to Food and Pharmaceutical Tampering and Fraud". S.F. Platek, **N. Ranieri**, J.B. Crowe and K.A. Wolnik, Monterey, CA, April 19-22, 1997

- **Southern Ohio Regional Poison Control System's Regional Toxicology Conference, University of Cincinnati Medical Center**
"Investigation of Tampering and Diversion". S.F. Platek, N. Ranieri, J.B. Crowe and K.A. Wolnik, in Cincinnati, OH, April 27, 1996
- **University of Cincinnati, College of Pharmacy**
"Microscopic Analysis of Selected Cases Involving Product Tampering and Pharmaceutical Counterfeiting". S. F. Platek, **N. Ranieri** and J.B Crowe, Cincinnati, Ohio, November 1, 1996
- **The Great Lakes Microscopy Conference 1995, GLeMA'95**
"Analysis of Suspect Food and Beverage Product Tampering and Pharmaceutical Counterfeiting by Light Microscopy and SEM/EDX Analysis". S. F. Platek, **N. Ranieri** and K. A. Wolnik, October 12-14, 1995
- **University of Cincinnati, College of Medicine**
"Selected Topics Related to Analysis of Food and Beverage Product Tampering and Pharmaceutical Counterfeiting by Light Microscopy and SEM/EDX Analysis". S. F. Platek, **N. Ranieri** and K. A. Wolnik, Cincinnati, Ohio October 17, 1995
- **University of Cincinnati, College of Pharmacy**
"Analysis of Suspect Food and Beverage Product Tampering and Pharmaceutical Counterfeiting by Light Microscopy and SEM/EDX Analysis". S. F. Platek, **N. Ranieri** and K.A.Wolnik, Cincinnati, Ohio November 17, 1995
- **Sixth International Meeting of SCANNING**
"Forensic Scanning Electron Microscopy Related to the Pepsi "Tampering" of 1993 (and Related Food and Drug Samples)". S. F. Platek, **N. Ranieri** and K. A. Wolnik, Applications of Scanning Microscopy in Forensic Science, Charleston, SC, May 19, 1994
- **Mid- Western LEICA User's Conference**
"Use of the Scanning Electron Microscope in Food and Drug Forensics". S. F. Platek, **N. Ranieri**, Toledo, OH, August 10, 1994
- **Annual Meeting of the Central Section Association of Official Analytical Chemists** "Forensic Scanning Electron Microscopy and Energy Dispersive X-ray Analysis of Samples Associated with the Pepsi "Tamperings" of 1993. S. F. Platek, **N. Ranieri** and K. A. Wolnik, in Lexington, KY, October 24, 1994

TECHNIQUE RECOGNITION:

- **Stopping the Poison Pills: Combatting the Trafficking of Illegal Fentanyl From China**
Assisted DEA in their investigation of a massive overdose outbreak in the Nashville, Tennessee area. Linking counterfeit Percocet tablets containing fentanyl obtained from China to the point of manufacture; FDA's Forensic Chemistry Center (FCC) analyzed tablet dies and tablet punch tips seized from the suspects and compared them with counterfeit Percocet tablets from the victims. The FDA-FCC used 3D image analysis profilometry to determine the tablet debossing profiles and overall surface morphology of the counterfeit Percocet tablets were consistent with the seized tablet punch tips. The toolmark evidence was used in the successful prosecution of eight defendants linked to the manufacture and distribution of the counterfeit Percocet pills containing

fentanyl that caused at least seven hospitalizations and one death. Statement of Daniel G. Burke, Senior Operations Manager of USFDA's criminal law enforcement arm, Cybercrime Investigations Unit, Office of Criminal Investigations, ORA, Department of Health and Human Services Before the Caucus on International Narcotics Control United States Senate October 2, 2018

MEDIA COVERAGE OF FDA CD3 DEVICE

- 2012 - Margaret A. Hamburg, M.D. Commissioner of Food and Drugs unveiled to the American people, as well as the World, FDA's new tool used to fight against counterfeiters of pharmaceuticals finished dosage form. This new FDA device was designed and developed by **Nicola Ranieri** and Mark Witkowski. Numerous websites quickly spread the media coverage of FDA's new tool. Some examples of the coverage were kept for the record:
 - CNN.com – "FDA unveils new device that detects counterfeit drugs"
 - Securing Pharma – "FDA may offer counterfeit detection device to other bodies"
 - Device Space – "FDA Unveils Device to Detect Counterfeit Meds"
 - Fox Wilmington – "FDA unveils new device to detect counterfeit drugs"
 - Hawaii News – "FDA unveils new device to detect counterfeit drugs"
 - Cutting-Edge.com – "Cutting-edge counterfeit drug tool unveiled"
 - Medical Daily – "FDA Unveils New Device that Detects Fake Drugs"
 - MedPage Today – "New FDA Device Helps ID Fake Drugs"
 - MedReps.com – "FDA looks to curb pharmaceutical sales of counterfeit drugs with new device"
 - WalterClark.com – "New FDA Device Detects Counterfeit Drugs"

AWARDS:

HHS SECRETARY KATHLEEN SEBELIUS AWARD

- A competition award that recognizes employees and their achievements in using new concepts to solve important challenges in the workplace HHS *Innovates* Award, Secretary's Pick for the outstanding work on the development and implementation of the Counterfeit Detection Device (CD3). The HHS Secretary selected this innovation for the best annual HHS *Innovates* Award 2013.

FDA COMMISSIONER'S SPECIAL CITATIONS

- Anti-Malarial Field Portable Instrument Evaluation (FPIE) Team 2016
- President's Interagency Working Group 2007
- Work on the Unapproved Botulinum Toxin Substitution Investigation Team 2006
- Interagency Chromium Cow Emergency Response Team 2005
- Adulterated Baby Food Emergency Response 2005
- Liberty Shield Response Team 2004
- Tobacco Working Group 1994

LEVERAGING / COLLABORATION AWARDS

- Anti-Malarial Field Portable Instrument Evaluation (FPIE) Team 2016
- Leveraging/Collaboration Award - Operation Bait and Switch Group with Customs and Border Protection and Postal Service 2006

TODD M. BOZICEVICH AWARD

- Special Recognition Award, ORA Education Collaboration of the Year Award – DHRD Course IM214 & IM216 - 2016

SCIENTIFIC ACHIEVEMENT AWARDS

- ORA Scientific Achievement Award - Excellence in Laboratory Science 2007 for designing,

developing, and implementing a device that is useful for the rapid screening and detection of suspect counterfeit pharmaceutical products and packaging

- ORA Scientific Achievement Award - Excellence in Laboratory Science 2001 for investigation and characterization of puncture holes in food and pharmaceuticals containers providing immediate information concerning the nature of consumer complaints in product tampering cases

INTER AGENCY HONORS AND EXCEPTIONAL AWARD

- Operation Pill Pusher - For exceptional coordination and teamwork to protect public health by creating an authentic and a diverted drug library to be used in the enhancement of counterfeit drug screening 2016
- Office of Criminal Investigations "Special Agent" Award - Appreciation of the Significant Contributions to the "Mission of The Office of Criminal Investigations 2007

FDA/ORA GROUP RECOGNITION AWARDS

- Operation Inferno, Illicit drugs and adulterated supplements from entering into the U.S. through collaboration and partnership with other agencies 2018
- Counterfeit Drug Detection Device Procurement 2017
- Member of the Counterfeit Drug Detection Device Procurement Group 2017
- Certificate of Appreciation - Infant Dietary Supplement Contamination Compliance Team 2017
- Member of the Operation Pill Pusher 2015
- Counterfeit and Unapproved Oncology Drug Analytical Work 2013
- Scientific Data Management 2013 Systems Team 2013
- Exceptional dedication, innovation and group effort in designing, building, training, and implementation of a portable counterfeit detection device (CD3) 2011
- Internet Pharmacies Analytical Working Group 2010
- Suspect Counterfeit / Unapproved Flu Medicines Rapid Response Analysis 2010
- Counterfeit Toothpaste Forensic Analysis Team 2009
- Controlled Substances Hospital Tampering 2009
- Illegal Imported Prescription Drug Forensic Analysis 2009
- Pet Food and Feed Contaminant Response 2008
- Counterfeit Animal Pharmaceutical Analytical Group 2008
- Interagency collaboration between FCC (Nicola Ranieri) and WEAC (Winchester Engineering & Analytical Center) on Counterfeit Drug Detector (Version 1) 2007
- Counterfeit Atorvastatin Investigation Work 2004
- Counter-terrorism Analytical Methods Work 2003
- Counterfeit Pharmaceuticals Investigation Work 2002
- Fraudulent Findings at a foreign Active Pharmaceutical Ingredients (AP) manufacturer 1997
- Excellent service assisting in the determination of Clenbuterol residue in tissues 1996
- Outstanding forensic analysis and coordination contributing to the successful conviction of a lawyer for filing a false claim 1995

OUTSTANDING SERVICE AWARDS

- Counterfeit Animal Pharmaceutical Analytical Group 2008
- Contaminated Toothpaste Analytical Task Force 2008

FDA AWARDS

- Award of Merit - Guatemala Measles Vaccine Forensic Work 2000
- Award of Merit - Adulterated/Misbranded Pharmaceuticals Investigation work 2000
- Exceptional dedication and scientific leadership in the forensic analysis of prescription drugs and controlled substances related to a large scale, illegal prescription drugs importation ring 2009

- Innovation and effort into establishing a FluMeds Image Library for use in field examinations of flu medications entering the United States during the swine flu outbreak 2009
- Satisfactory Completion of all Requirements Level 1 Analyst Certificate 2005
- Bring Your Child to Work Day for excellent forensic display 2004
- Participating in the development of Counter-terrorism Analytical Work 2003
- Providing imaging support to FCC individuals as a resident expert in image analysis and visual aids for outreach, information exchange and technology transfer 2003
- Teamwork supporting FCC employees in reaching FCC goals 2002
- Contribution to various types of analyses performed at FCC 2002
- Completion of documentation and data tables related to high profile counterfeit drug cases 2001
- Winner of the Research/Manuscript images for the cover image for the March/April 2000 issue by SCANNING, The Journal of Scanning Microscopies 2001

PERFORMANCE AWARDS

- Technical oversight and design of numerous scientific posters 2000
- Assistance and guidance to FCC in the area of audio visual needs 2000
- Research Development and Implementation of an Integrated Data Handling
- Storage System for casework documentation and database in the Microscopy Laboratory 1998
- Assisting FCC move to new building 1998
- Assisting and training septa imaging to the Indiana State Police Lab in the investigation of the largest multiple homicide 1997
- Extraordinary work on the Cefaclor case which supported the largest drug recall in FDA history 1997
- Assisting other FCC employees with imaging and presentation difficulties 1997
- Special act of FCC service 1995
- Excellent service 1993
- Excellent service 1992
- Excellent service 1991
- Excellent service 1990

COURT TESTIMONY EXPERIENCE

- 2018 - March 19, 2018: U.S. v. Barrett, et al - Fentanyl Overdose – Testified on 3D Profilometry on tablets to tablet punch tips (TPT) and tablet to tablets 3D image analysis. The jury found three defendants guilty on all counts as to all victims. They all now face a mandatory minimum sentence of 20 years, with no possibility of parole. This case was the result of work by the DEA, Murfreesboro PD, RCSO, TBI, FDA, the ME's office, and others in law enforcement.
- 2010 - presented to a federal grand jury in Yakima, Washington, the Lynn Schneider Trial; count indictment with the wrongdoing of tampering and the chemical adulterations with regard to narcotics – Testifying in the Yakima Courts were Jonathan Litzau, **Nicola Ranieri**, Dave Jackson, Caroline Kelly, Barbara Barnes, and John Crowe under the guidance of AUSA, OCC Jim Smith. The defended was found guilty and received a prison sentence.
- 2003 - Nicola Ranieri, Laura Ciolino, and Angie Mohrhaus to testify in the State of Florida for the Office Of The State Attorney Tenth Judicial Circuit under the guidance of Victoria J. Avalon Assistant State Attorney. **Nicola Ranieri** was subpoenaed to testify for the analysis of syringe needle puncture characterization on glass vial rubber stoppers in the case of "Winter Haven Vials" trial. After deposition and consultation with attorney no cross examination was conducted. The defended after a review of the evidence provided from Mr. Ranieri and other FCC work plead guilty.

ANTI-COUNTERFEIT INSPECTIONS

Counterfeit Active Pharmaceutical Ingredient Inspections:

- CSOs, Chemists, and Biologist **Ranieri** conducted counterfeit active pharmaceutical ingredient (API) investigations, April 2013
- Amneal Pharmaceuticals, LLC located at 209 McLean Boulevard, Patterson, NJ 07504. Issued an FDA-482, March 22, 2012
- CorePharma, LLC located at 215 Wood Avenue, Middlesex, NJ 08846-2554. No action was taken, March 20, 2012
- Actavis Elizabeth LLC located at 200 Elmora Avenue, Elizabeth, NJ 07202. Conducted pursuant to Ad hoc FACTS Assignment 1400488, Operation ID 6085447. Issued an FDA-482 to Anthony J. Delicato, Head of Quality, NJ SOD Operations, for the Elizabeth, NJ facility, March 13, 2012
- Actavis Edison, 47 Brunswick Avenue, Edison, NJ. Issued an FDA-482 to Anthony J. Delicato, Head of Quality, NJ SOD Operations, March 12, 2012
- 1998 - Foreign Inspection on Cefaclor pharmaceutical company as well as GMP.
- 1997 - Foreign Inspection on Cefaclor pharmaceutical company as well as GMP.
- 1997 - Interpreter for the FCC Foreign Inspection Team (English/Italian and Italian/English).
- 1996 - Foreign Inspection on Cefaclor pharmaceutical company as well as GMP on other pharmaceutical companies.
- 1996 - Interpreter for the FCC Foreign Inspection Team (English/Italian and Italian/English).

SOCIETY AND MEMBERSHIPS

- 2008 - Microscopy Society of the Ohio River Valley (MSORV). MSORV is a local affiliated society of the Microscopy Society of America (MSA) and the Microbeam Analysis Society (MAS).
- 2005 - Media Cybernetics Image Analysis Zone Forum – Community discussions and collaboration for IA users for Media Cybernetics Members.

LANGUAGES

- Proficient in two languages: Italian and English.

TRAVELS

- Traveled to the following areas for work-related tasks: Accra (Ghana), Vientiane [Laos (South East Asia)] Frankfurt (Germany), Milan (Italy), Leon (France), Miami (Florida, USA), San Francisco (California, USA), Los Angeles (California, USA), Parsippany (New Jersey, USA), Chicago (Illinois, USA), Washington D.C.

FDA/FCC SPECIAL ASSIGNMENTS AND ADVISORY ACTIVITIES

- 2011 - Special arrangements to conduct a scanning on diverted and counterfeit products in San Juan, Puerto Rico, one of the largest case/evidence onsite analyses since working for the FDA/FCC. This work involved using the portable Alternate Light Source (ALS) system methods and the FCC Patented device Counterfeit Detector 3 (CD3) developed by Nicola Ranieri and Mark Witkowski. The work resulted in scanning over 14,000 bottles and boxes in three days, something unheard of in the history of the FCC. The findings will be used to prosecute a suspected criminal for selling diverted and counterfeit products.
- 2009 - *Advisory Imaging Panel Meeting* at the National Library of Medicine (NLM) in Bethesda, MD. The meeting involved imaging expertise. The imaging panel was implemented by the NLM and named as the Solid Dose Pharmaceutical Imaging Initiative Photographic Imaging Guidelines Expert Panel. The meeting was in Bethesda, Maryland. Other members of this imaging panel were from: The Center for Imaging Science Rochester Institute of Technology; The Laboratory for the Study of Visual Appearance Dept. of Computer Science Columbia University; The Envisioning Science Program Initiative in Innovative Computing

Harvard University; and a Photographer from the Smithsonian Institution. Others that attended the meeting were from the National Institute of Health (NIH) and from the US Pharmacopeia.

- 2001 - Subpoenaed as an expert witness in U.S. Federal Court (Columbus, Ohio). Testimony regarding forensic analysis of unapproved drugs evidence (Laetrile and hydrazine sulfate).

OTHER SIGNIFICANT INFORMATION

- INTER AGENCY COLLABORATION: 2011 – Presentation: Drug Enforcement Agency (DEA)/Special Testing and Research Laboratory (STRL) collaboration work on toolmarks analysis of tablets and tablet punch face. Work conducted with DEA/STRL Senior Forensic Chemist Roxanne Franckowski at the FDA/Forensic Chemistry Center (FCC) facility in Cincinnati, Ohio. Collaboration work and training for Dr. Franckowski was conducted in the area of solid dosage tablet toolmark analyses, as well as assisting in the collaborative work conducted at FCC on toolmark tablet and punch face analyses. Mr. Ranieri also trained Dr. Franckowski on various imaging methods, processing, and examination of punches/tablets using the 2D and 3D imaging systems employed by the FCC. Dr. Franckowski received hands-on training which included, but was not limited to, acquiring images via Stereo Light Microscope (SLM) setup, Hirox 2D/3D imaging system, and Alicona Infinite Focus Microscope 3D imaging system. Images acquired were processed using the software provided by the manufacturer such as ImagePro Plus. Subsequent to the hands-on training, Dr. Franckowski worked with Mr. Ranieri to further develop methods for imaging solid dosage tablets and punches, which could be used by both DEA and FDA. The work was conducted in the FCC laboratory Trace Examination Section under the management of the Organic Branch Director, Dr. Duane Satzger.
- METHOD AND DEVICE DEVELOPMENT FOR INTRA and INTER AGENCIES: In 2005 Nicola Ranieri and Mark Witkowski presented the initial prototype to the FCC management. The demonstration was called “Development of a Multi- wavelength Light Source Method for Tablets and Excipients for use in the Analysis of Suspect Counterfeit Product”. The objective of the development of this method was to design a multi-wavelength light source system that delivered practicality, reduced analysis time by conducting analysis in real-time (on the spot), and be cost efficient and adaptable. The method development involved the analysis of products/substrates using two types of multi-wavelength devices, a commercially available large heavy box Crimescope (CS-16) and a hand held crimescope prototype, developed for this purpose, a multi-wavelength device, we initially called it the ALS-nm4. Later the name of the device was changed to Counterfeit Detector version 1 (CD1). Over the next nine years modifications to the initial device were made based on learned requirements and suggestion by many users. The device has gone through four generations, CD1, CD2, CD3, and CD3+.
- INTRA AND INTER AGENCIES DOCUMENT LANGUAGE TRASLATOR: 1989 - Presentation: translator for manufacturing contracts, court documents, COA's, and other (Italian to English) for FCC, CinDO, OCI, and the Department of Justice for FCC related work. In 1996 through 2003 a multi-agency investigation resulted in the Plea of Guilty to felony for conspiracy and defrauding the FDA resulting in a fine of \$33 million dollars, among the largest monetary penalties ever imposed in a criminal pharmaceutical prosecution. This case represented the first time that a foreign corporation has been criminally punished based upon defrauding the FDA concerning a drug product, which it manufactured wholly outside the United States but marketed to the American public.
- OTHER METHOD DEVELOPMENT FOR INTRA AGENCIES:
 - 2011 - Implemented a new method by the development/template

generations for the Mideo Caseworks for the International Mail Facilities (IMFs)

- 2007 - 2011 - Implemented the method by the development/template generations for the Mideo Caseworks which was the NEW method for sample / casework photodocumentation at the Forensic Chemistry Center
- 1999 - Developed, constructed and implemented the system for sample / casework photodocumentation at the Forensic Chemistry Center. Developed photodocumentation methodology and instructed all staff scientists / analysts in the capture, collection, storage and processing of photodocumentation images
- 1998 - Developed, constructed and implemented the system of an Integrated Data/Image Handling Storage System for casework photodocumentation and image/object data base currently used in the FCC's Microscopy / Microanalysis Laboratory
- 1998 - Developed electron microscopy and energy dispersive x-ray map image capturing capabilities and reproduction / publication methods currently used in the FCC's Microscopy / Microanalysis Laboratory. The system now permits sample / casework photodocumentation at the Forensic Chemistry Center